EXHIBIT J

ETHICON INC.
a Johnson & Johnson company

Document Name (#): RMR-0000044
Revision: 1

RISK MANAGEMENT REPORT (LEGACY) FOR TVT AND TVT-O

Revision History for (RMR-0000044)

Revision # *(Insert the Rev # in ascending order)*	Summary of Change *(Describe the change, and the section of the form where the change occurred.)*	Change Order # *(Insert the associated change order#)*	Originator *(Insert the author of the document or change)*
1	Original Issue	CO-00120496	M. Viscido

Originator Name/Title	Signature	Date
Michael Viscido Sr. Project Manager, Product Risk	(Electronic Signature)	

Name/Title	Signature	Date
Mark Yale Director, WW Risk Management/QE	(Electronic Signature)	
David Robinson, MD Medical Director	(Electronic Signature)	
Dan Smith Engineering Fellow, Research & Development	(Electronic Signature)	
Neal Brunner, WW Quality Engineering Manager	(Electronic Signature)	

Product Scope:

This Risk Management Report covers the Tension-free Vaginal Tape (TVT) System, the GYNECARE TVT System with Abdominal Guides and the GYNECARE TVT Obturator System packaged as sterile. Included across these products are clear and blue mesh as well as Laser cut and mechanically cut meshes listed below.

This includes all product numbers listed below:

810041A	810041B	810041BL	810051	810081
810061	830041A	830041B	830041BL	810081L

Product Description (include sub-systems):

Description:

The various TVT configurations consist of 1 or more of the following items:
TVT Single-Use Device, provided sterile (available separately)
TVT Reusable Introducer, provided non-sterile (available separately)
TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately)
GYNECARE TVT *with abdominal guides* - Disposable Abdominal Guides and Couplers, provided sterile (available separately in some locations)
GYNECARE TVT Helical Passers
GYNECARE TVT Atraumatic Winged Guide

TVT DEVICE

The TVT device is a sterile single use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Colour index. Number 74160) PROLENE® polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE® polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE® polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE® mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

TVT INTRODUCER

The TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

TVT RIGID CATHETER GUIDE

The TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

GYNECARE TVT ABDOMINAL GUIDE

The GYNECARE TVT abdominal guide is a sterile disposable instrument intended to facilitate passage of the GYNECARE TVT device. Two abdominal guides are included in each kit with the GYNECARE TVT couplers.

GYNECARE TVT COUPLER

The GYNECARE TVT coupler is a sterile disposable polypropylene connector used to connect the GYNECARE TVT abdominal guide to the GYNECARE TVT needle. Two couplers are included in each kit with the two abdominal guides.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT Obturator device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT Obturator device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

Indications:

The GYNECARE TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. GYNECARE TVT introducer, rigid catheter guide and GYNECARE TVT abdominal guides and couplers are available separately and intended to facilitate the placement of the GYNECARE TVT device. The reusable TVT handle and rigid catheter guide are also used to facilitate device placement.

Anticipated operating conditions considered and covered by risk analysis and assessment:

Conditions found in normal operating theatre (i.e. room temperature and humidity in operating room, emergency room, etc.)

Anticipated use environments considered:

Typical operating theatre

Physical and functional boundaries:

The device is intended to be used within the boundaries of the sterile field.

Report Prepared by:

M. Viscido

Worldwide Risk Management

Description of changes from last revision:

Not applicable. Initial Issue.

List dates of all postproduction reviews:

The TVT/TVT-O family of devices is defined as a "Legacy Devices" for Ethicon, Inc. As such there are no additional post-PRA reviews scheduled for this device. Methods are in place to obtain relevant production and post-production information as defined in the execution of our production and/or Design Control processes.

Reference Documents (As Applicable):

Explain/Describe and advise of location:

- Risk Management Plan – Ethicon, Inc. – Legacy Devices, RMP-0000001, Rev. 2 (Central File Room, WWRM Files)
- PR602-003 Company Procedure for Medical Device Risk Management Plan (ECCS), Rev. 13
- PT-0005674 Risk Management Protocol Ethicon, Inc. – Process For Legacy Devices, Rev. 2

Harms-Hazards Summary Table*:

1) Below is a summary table that provides a listing of the Harms/Hazards associated with this device

Harm	Severity of Harm	Hazard	Estimated Frequency of Harm
Blood Loss	10	Improper dissection technique	2
		Device Passage causes puncture/laceration	
Erosion - Urinary Tract	10	Local irritation/transitory foreign body response	2
		Dissection technique/tools	
		Improper implant positioning	
		Improper wound closing	
Erosion - Vagina	10	Local irritation/transitory foreign body response	4
		Dissection technique/tools	
		Improper implant positioning	
		Improper wound closing	
Extended Surgery	9	Improper dissection technique	4
		Incorrect patient position	
Fistula	9	Improper dissection technique	0
		Device Passage causes puncture/laceration	
Infection	10	Existing infection	4
		Cross contamination	
		Compromised device sterility	
Internal Organ Damage	10	Improper dissection technique	4
		Device Passage causes puncture/laceration	
		Improper implant positioning	

Harm	Severity of Harm	Hazard	Estimated Frequency of Harm
Nerve Damage/Paine (major)	9	Improper dissection technique	4
		Incorrect patient position	
		Residual foreign body	
Unintended Tissue Reaction	9	Non-biocompatible materials	4
		Transitory foreign body response	
		Local irritation	
Tissue Damage	9	Improper dissection technique	0
		Device Passage causes puncture/laceration	
		Sum of Harm Frequency (ORR)	**28**

*Hazards listed may not have led to the actual harm but are included to represent a worst-case scenario.

Risk Analysis:

The risk analysis process was conducted in accordance with the Company Procedure for Medical Device Risk Management Plan, PR602-003, Risk Management Protocol: Ethicon, Inc. – Process For Legacy Devices, PT-0005674, Rev. 1 and RMP-0000001 Risk Management Plan Ethicon, Inc. – Legacy Devices. A flowchart description of activities conducted is listed in Appendix A and the results of the activities are provided in Appendix B.

As required by RMP-0000001, when the Overall Residual Risk is Moderate an additional review of comparable devices of the FDA MAUDE database was conducted. The review results are provided in Appendix D. This review did not indicate any additional harms/hazards to those that were indicated by review of the labeling and the internal complaint database.

FMEA's (ECCS Document Numbers):

aFMEA:

- Not required for this legacy device risk management report

dFMEA:

- Not required for this legacy device risk management report

pFMEA:

- Not Required for this legacy device risk management report

Frequency of Harm Assessment performed by:

Medical Director: Dr. David Robinson
Sr. Project Manager, Product Risk: Michael Viscido
Senior Engineering Fellow: Dan Smith

Overall Residual Risk Assessment

Overall Residual Risk Score: 28 Overall Residual Risk Level: ***Moderate***

Risk Benefit Analysis Required: *NO*

Risk Management Report Conclusion

Approval of this Risk Management Report signifies that the team has:

a) Successfully completed the Risk Management Plan defined in *documents* # PT-0005674 and RMP-0000001.

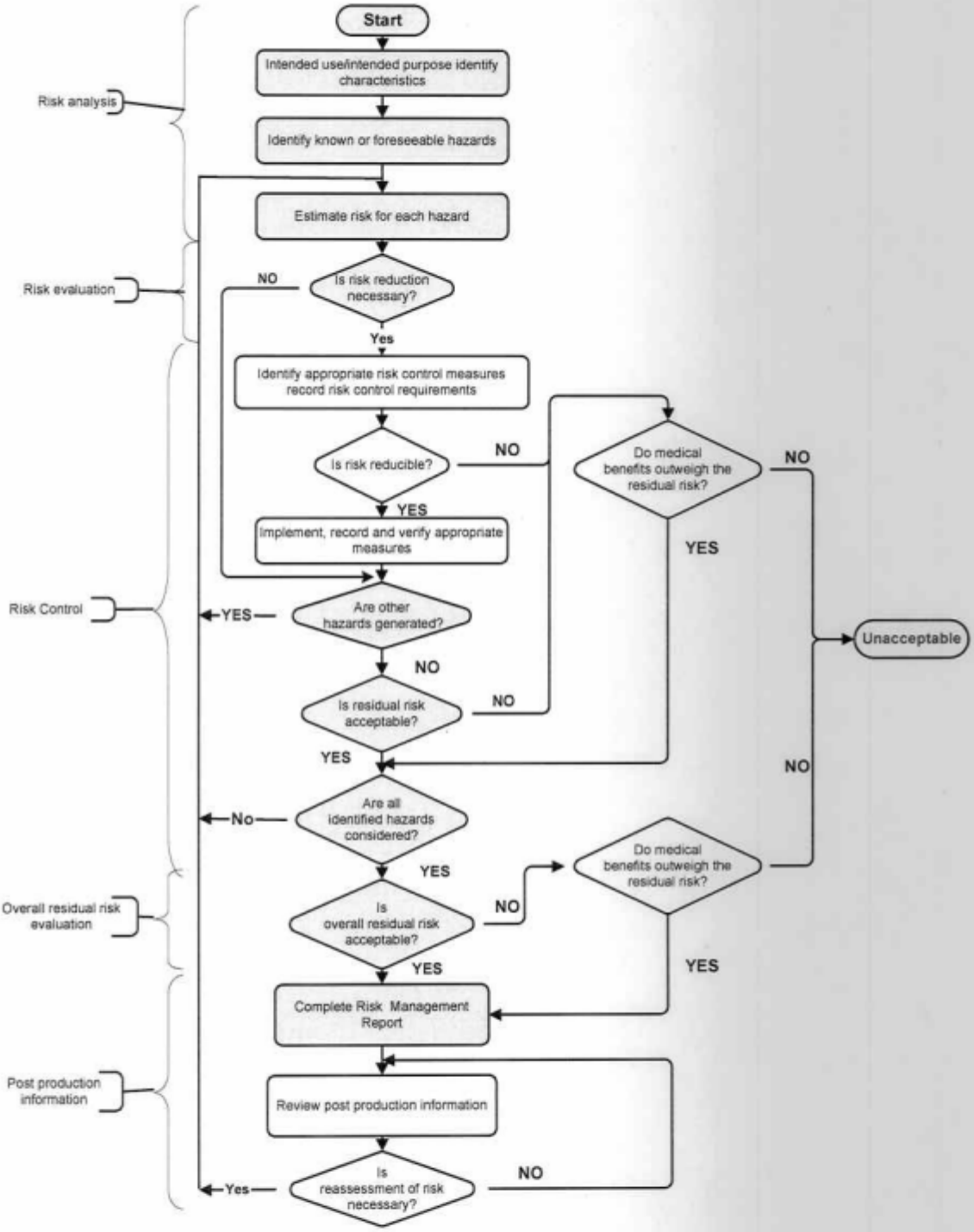
b) Shown that the Overall Residual Risk is considered acceptable per the requirements defined in PR602-003

Electronic approval of this report occurs in ECCS per requirements defined in PR602-003 step 6 (new reports).

Appendices

Appendix	Description
A	Process Flow
B	Risk Management Process Results
C	Relevant Product Labeling (US & EU-Great Britain)
D	FDA MAUDE Database Review

Appendix A – Process Flow[1] (Actual Flow Highlighted in Yellow)



[1] This Process flow diagram was copied from PR602-003 Revision 12.

Appendix B – Risk Management Process Results: Harms/Hazards Table

No.	Harm	Severity	Hazard*	Frequency of Harm (per 1 million units sold)	Frequency of Harm Rating	Harm/Hazard Information Source**	Label section (if applicable)
1	Blood Loss	10	Improper dissection technique	17	2	Label/Complaint Data	Warnings
			Device Passage causes puncture/laceration				
2	Erosion - Urinary Tract	10	Local irritation/transitory foreign body response	17	2	Complaint Data	-
			Dissection techniques/tools				
			Improper implant positioning				
			Improper wound dosing				
3	Erosion - Vagina	10	Local irritation/transitory foreign body response	97	4	Complaint Data	-
			Dissection techniques/tools				
			Improper implant positioning				
			Improper wound dosing				
4	Extended Surgery	9	Improper dissection technique	42	4	Complaint Data	-
			Incorrect patient position				
5	Fistula	9	Improper dissection technique	8	0	Complaint Data	-
			Device Passage causes puncture/laceration				
6	Infection	10	Existing infection	86	4	Label/Complaint Data	Adverse Reaction/Warnings
			Cross contamination				
			Compromised device sterility				
7	Internal Organ Damage	10	Improper dissection technique	55	4	Label/Complaint Data	Adverse Reaction/Warnings
			Device Passage causes puncture/laceration				
			Improper implant positioning				
8	Nerve Damage/Pain (major)	9	Improper dissection technique	31	4	Label/Complaint Data	Warnings
			Incorrect patient position				
			Residual foreign body				
9	Unintended Tissue Reaction	9	Non-biocompatible materials	25	4	Label/Complaint Data	Warnings
			Transitory foreign body response				
			Local irritation				
10	Tissue Damage	9	Improper dissection technique	3	0	Label/Complaint Data	Adverse Reaction/Warnings
			Device Passage causes puncture/laceration				
				Sum of Harm Frequency	28		

* Hazards listed may not have led to the actual harm but are included to represent a worst case scenario

** A source listing of "General Risk" indicates a known risk, but not identified in either the label or from complaint data

Appendix B (cont.) – Risk Management Process Results: Complaint Information

Table 1: Initial Summary

No.	Count of cat_lvl2_desc cat_lvl2_desc	Total	Team Discussion Notes
1	Allergic Reaction	6	Unintended Tissue Reaction
2	Bent Needle	4	No Associated Harm
3	Bent wire	2	No Associated Harm
4	Bladder Erosion	1	Erosion - Uniary Tract
5	Bladder Laceration	1	Internal Organ Damage
6	Bladder Perforation	4	Internal Organ Damage
7	Bladder Perforation by Mesh	1	Internal Organ Damage
8	Bowel perforation	1	Internal Organ Damage
9	Customer perceived issue	1	No Associated Harm
10	Damaged product	4	No Associated Harm
11	Deformed Tip of Needle	4	No Associated Harm
12	Difficult sheath removal	3	No Associated Harm
13	Dislikes Package	2	No Associated Harm
14	Erosion: Urethral or otherwise unspecified	5	Erosion - Uniary Tract
15	Foreign matter	2	Infection
16	Groin Pain	12	Nerve Damage/Pain(3)/Pain-minor(9)
17	Hematoma formation	1	Blood Loss
18	In spec/Does not meet customer requirements	5	No Associated Harm
19	Inadequate Labeling	1	No Associated Harm
20	Inadvertent Retention of the Coupler	1	No Associated Harm
21	Incisional Bleeding	1	Blood Loss
22	Incorrect fit: needle and introducer	7	No Associated Harm
23	Incorrectly assembled	1	No Associated Harm
24	Infection	29	Infection(18)/No Associated Harm (11)
25	Intra Operative Complication	5	Blood Loss(1)/No Associated Harm (4)
26	Intra-Operative Complication	16	Blood Loss(1)/No Associated Harm (5)/Extended Surgery (10)
27	Lower Abdominal Pain	2	Nerve Damage/Paine(1)/No Associated Harm (1)
28	Mesh broken	5	No Associated Harm
29	Mesh Frayed	8	No Associated Harm
30	Mesh Fraying	3	No Associated Harm
31	Mesh Kinked- Out of Package	1	No Associated Harm
32	Mesh Slippage	1	Failure of Treatment
33	Missing Component	2	No Associated Harm
34	Needle Broken	2	No Associated Harm
35	Needle detaches during use	2	No Associated Harm
36	Needle difficult to remove from handle	5	No Associated Harm
37	Not Specified	3	No Associated Harm
38	Open Seal	8	Infection
39	Plastic needle too difficult to remove from the helical passer	2	Extended Surgery
40	Plastic sheath splitting/cracking/breaks	2	Extended Surgery
41	Plastic tube damage/breakage	8	No Associated Harm
42	Post Operative Lower Extremity Pain	18	Nerve Damage/Paine(6)/Pain-minor(11)/No Associated Harm (1)
43	Post-Operative Complication	45	No Associated Harm (37)/Erosion-Vaginal (2)/Unintended Tisue Reaction (4)/Failure Of Treatment (5)/Infection (2)/Pain-Minor (7)/Pain (1)/Blood Loss (2)/Fistula (3)/Tissue Damage (1)/Internal Org Damage (1)
44	Post-operative complications	20	(combine with above)
45	Post-Procedural Incontinence	16	Failure of Treatment
46	Premature separation of plastic sheath from mesh (out of package)	2	No Associated Harm
47	Premature separation of the plastic needle from the helical passer	3	Extended Surgery (1)/No Associated Harm (2)
48	Premature seperation of plastic sheath from mesh (during use)	1	No Associated Harm
49	Product Caught in Seal	1	Infection
50	Product loose in packaging	1	No Associated Harm
51	Sheath Splits/Cracks/Breaks	3	No Associated Harm
52	Sheath Splitting/Cracking/Breaks Prior to Use	2	No Associated Harm
53	Tip/Tube bent during use	1	No Associated Harm
54	Torn Mesh	1	No Associated Harm
55	Urethral Perforation	1	Internal Organ Damage
56	Urinary retention	10	Internal Organ Damage
57	Vaginal Exposure	18	Erosion Vagina(33)/No Associated Harm (1)
58	Vaginal Extrusion	16	(combine with above)
59	Vascular Injury	2	Internal Organ Damage
	Grand Total	335	

Appendix B (cont.) – Risk Management Process Results: Complaint Information

Table 2: Final Summary

No.	Harms (9/10 Severity)	Total
1	Blood Loss	6
2	Erosion - Urinary Tract	6
3	Erosion Vagina	35
4	Extended Surgery	15
5	Fistula	3
6	Infection	31
7	Internal Organ Damage	21
8	Nerve Damage/Paine(major)	11
9	Unintended Tissue Reaction	10
10	Tissue Damage	1
11	Pain-Minor*	27
12	Failure of Treatment*	22
13	No Associated Harm **	147
	Sub-total	335

* Indicate harms with a severity ranking of 8 or less, not related to the device or considered normal, temporary and/or minor procedural/device effects. These are not considered in the Overall Residual Risk calculation

Appendix B – Risk Management Process Results: Sales Information

Tension Free Vaginal Tape (TVT)

Sales By Year **Quantity In Eaches[1]**

TRUE_DEMAND	2006	2007
810041A-GYNECARE TVT AA	6,370	5,638
810041B-TVT DEVICE w/Blue mesh 1PK	46,223	33,345
810041BL-TVT DEVICE (1PK) LCM	846	9,382
810051-TVT INTRODUCER	683	594
810061-TVT CATHETER GUIDE	854	875
830041-TVT DEVICE (3PK)	2,277	2,148
830041B-TVT DEVICE w/Blue mesh 3 PK	16,019	3,705
830041BL-TVT DEVICE (3 PK) LCM	2,470	15,078
810081-GYNECARE TVT-O	102,191	76,268
810081L-GYNECARE TVT-O LCM	5,193	30,044
Total:	183,126	177,077
Grand Total:		**360,203**

[1] Data fromSCORE Database.

Appendix C – Relevant Product Labeling: US

(See PDF version for Labeling)

GB USA **Tension-free Vaginal Tape (TVT) System – Instructions for Use**

TVT Single Use Device
TVT Reusable Introducer
TVT Reusable Rigid Catheter Guide

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

Important:
This package insert is designed to provide instructions for use of the Tension-free Vaginal Tape single use device, reusable introducer, reusable rigid catheter guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the TVT device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION (System)
TVT consists of the following:

- TVT Single-Use Device, provided sterile (available separately)
- TVT Reusable Introducer, provided non-sterile (available separately)
- TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately)

TVT DEVICE
The TVT device is a sterile single use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Colour index. Number 74160) PROLENE® polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.
PROLENE® polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE® polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE® mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

TVT INTRODUCER
The TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

TVT RIGID CATHETER GUIDE
The TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

INDICATIONS
The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT introducer and rigid catheter guide are available separately and intended to facilitate the placement of the TVT device.

INSTRUCTIONS FOR USE

The patient should be placed in the lithotomy position taking care to avoid hip flexion greater than 60°.

The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e. a vaginal midline entry with a small paraurethral dissection to initially position the needle and two suprapubic skin incisions. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into the paraurethral dissection. Then, two abdominal skin incisions of 0.5 – 1 cm are made, one on each side of the midline just above the symphysis not more than 4 – 5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is fixed around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, the bladder should be empty. The threaded end of the introducer is screwed into the end of one of the needles.

Using the introducer, the needle is passed paraurethrally penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should rest in the palm of the "vaginal" hand. If you are right handed this means that the left hand generally is the one to be used for needle guidance. With the other hand grip the handle of the introducer gently. Now introduce the needle tip into the retropubic space. Once again observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally i.e. in the frontal plane. After passage of the urogenital diaphragm you will feel that the resistance is significantly reduced.

Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer thereby pressing the tip of the needle against the back of the pubic bone. Now, move the needle tip upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way.

When the needle tip has reached the abdominal incision, cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e. without tension, under the midurethra. Cut the tape close to the needles. Now, adjust the tape so that leakage is reduced allowing a few drops of urinary leakage to occur under stress. For this, use patient feedback i.e. coughing with a full bladder (approximately 300 ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths. Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in suboutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2 – 3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE® polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use TVT procedure for patients who are on anti-coagulation therapy.
- Do not use TVT procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the TVT system before employing the TVT device. It is important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE® mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the TVT procedure, in case of pregnancy delivery via cesarian section is recommended.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the TVT procedure. To minimize this risk, make sure to place the tape tension-free in the mid-urethral position.
- Do not contact the PROLENE® mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE® mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE® mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS
Animal studies show that implantation of PROLENE® mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS
(TVT Introducer, TVT Rigid Catheter Guide) To ensure the reliability and functionality of TVT Introducer and TVT Rigid Catheter Guide, clean the instruments before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments. Prior to cleaning, the TVT introducer should be separated into its component parts (handle and threaded shaft). The introducer is reassembled after cleaning and before sterilization.

Manual method
1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86° F to 95° F (30° C to 35° C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

Automated Method:
Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:
- Rinse/Wet Cycle Cold Water – 1 minute
- Wash 176° F (80° C) – 12 minutes
- Rinse Cycle – 1 minute
- Rinse Cycle – 12 minutes
- Final Rinse – 2 minutes
- Rinse with Demineralized water 176° F (80° C) – 2 minutes
- Dry 199.4° F (93° C) – 10 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS
(TVT Introducer, TVT Rigid Catheter Guide)
The TVT Introducer, TVT Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270° F to 284° F (132° C to 140° C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

INSTRUMENT MAINTENANCE
- TVT Introducer

Before each use, inspect the threaded parts of the inner shaft.
- TVT Rigid Catheter Guide

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

HOW SUPPLIED
The TVT device is provided sterile (ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices. The reusable TVT introducer, TVT rigid catheter guide are supplied separately, and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

STORAGE
Recommended storage conditions for the TVT single use device are below 25° C, away from moisture and direct heat. Do not use after expiry date.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

EC
Legal Manufacturer:

ETHICON® SARL
Rue du Puits Godet 20
CH-2000 Neuchâtel
Switzerland

Distributor (Europe):

ETHICON® Ltd.
Bankhead Avenue
Edinburgh, EH11 4 HE
United Kingdom

Distributor (USA):

Gynecare
a division of ETHICON®, Inc.
a Johnson & Johnson Company
Somerville, NJ
08876-0151

Appendix C (cont.) – Relevant Product Labeling: EU (English)

(See PDF version for Labeling)

GYNECARE* TVT

with abdominal guides

Tension-free Support for Incontinence

med abdominale styreenheder
Spændingsfri støtte til inkontinens

met abdominale geleiders
Spanningsvrij steunbandje tegen incontinentie

ja abdominaaliohjaimet
Jännityksetön inkontinenssituki

avec guides abdominaux
Soutien sans tension pour cure d'incontinence urinaire

mit Abdominalführungen
Spannungsfreie Unterstützung bei Inkontinenz

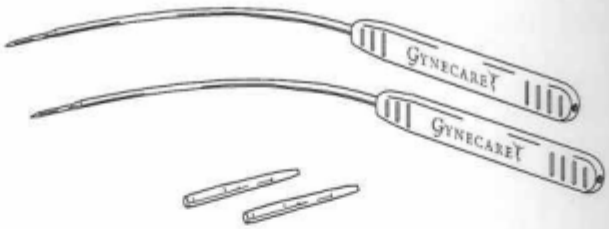
con guide addominali
Dispositivo tension-free per incontinenza

com guias abdominais
Suporte sem tensão para tratamento da incontinência

con guías abdominales
Sistema de suspensión sin tensión para la incontinencia

med bukguider
Spänningsfritt inkontinenssystem

με κοιλιακούς οδηγούς
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση



EC
Legal Manufacturer
ETHICON, Sàrl
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Switzerland

Manufactured for:

GYNECARE WORLDWIDE
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

389592.R03

RMC P17170/B

ENGLISH

GYNECARE* TVT *with abdominal guides*
Tension-free Support for Incontinence

GYNECARE TVT Single Use Device
GYNECARE TVT Reusable Introducer
GYNECARE Reusable Rigid Catheter Guide
GYNECARE TVT Abdominal Guides and Couplers

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

IMPORTANT:
This package insert is designed to provide instructions for use of the GYNECARE* TVT *with abdominal guides* Tension-free Support for Incontinence System, including single use device, reusable introducer, and reusable rigid catheter guide and disposable abdominal guides and couplers. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION (system)
GYNECARE TVT consists of the following:

GYNECARE TVT Single-Use Device, provided sterile (available separately)
GYNECARE TVT Reusable Introducer, provided non-sterile (available separately)
GYNECARE TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately)
GYNECARE TVT *with abdominal guides* - Disposable Abdominal Guides and Couplers, provided sterile (available separately in some locations)

GYNECARE TVT DEVICE
The GYNECARE TVT Tension-free Support for Incontinence device is a sterile single use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Colour index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7 mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT INTRODUCER
The GYNECARE TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the GYNECARE TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

GYNECARE TVT RIGID CATHETER GUIDE
The GYNECARE TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

GYNECARE TVT ABDOMINAL GUIDE

The GYNECARE TVT abdominal guide is a sterile disposable instrument intended to facilitate passage of the GYNECARE TVT device. Two abdominal guides are included in each kit with the GYNECARE TVT couplers.

GYNECARE TVT COUPLER

The GYNECARE TVT coupler is a sterile disposable polypropylene connector used to connect the GYNECARE TVT abdominal guide to the GYNECARE TVT needle. Two couplers are included in each kit with the abdominal guides.

INDICATIONS

The GYNECARE TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT introducer, rigid catheter guide and GYNECARE TVT abdominal guides and couplers are available separately and intended to facilitate the placement of the GYNECARE TVT device.

INSTRUCTIONS FOR USE

The patient should be placed in the lithotomy position taking care to avoid hip flexion greater than 60°. The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e. a vaginal midline entry with a small paraurethral dissection to initially position the needle and two suprapubic skin incisions. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into or passed through the paraurethral dissection. Then, two abdominal skin incisions of 0.5–1 cm are made one on each side of the midline just above the symphysis not more than 4–5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The GYNECARE TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is fixed around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, the bladder should be empty. The threaded end of the introducer is screwed into the end of one of the needles. If the abdominal access device is utilized, the tip of the GYNECARE TVT needle is inserted firmly into the distal (wider) end of the coupler. Ensure there is a snug connection between the coupler and GYNECARE TVT needle.

Abdominal Approach

GYNECARE TVT Tension-Free Vaginal Tape can be placed in position by either an abdominal or a vaginal approach. If the abdominal approach is utilized follow instructions above for paraurethral dissection. Holding the abdominal guide, gently insert it in a vertical, downward and saggital direction, through one of the abdominal incisions until the rectus fascia is reached. Firm pressure on the abdominal guide will pierce the rectus fascia and bring the abdominal guide into the retropubic space. Upon entering the retropubic space, the operator will feel a significant decrease in resistance. Pass the abdominal guide through the retropubic space taking care to keep it close to the posterior surface of the pubic bone. Using a vaginal finger (of the non-dominant hand), palpate the descent of the abdominal guide along the posterior surface of the pubic bone. When the tip of the abdominal guide is palpable just inferior to the pubic bone and superior to the anterior vaginal wall, rotate the tip of the abdominal guide towards the midline. Confirm that you are 1 cm lateral to the catheter guide (midurethra). Using digital counter-traction against the urogenital diaphragm, guide it out through the diaphragm and out the midline vaginal incision. Once the abdominal guide is brought through the vaginal incision, cystoscopy should be performed to ascertain that no bladder or urethral injury has taken place.

Empty the bladder once bladder integrity has been confirmed. Screw the threaded end of the introducer into the end of one of the needles. Insert the tip of the needle firmly into the distal (wider) end of the coupler. Next pick up the GYNECARE TVT device with attached coupler, and holding the abdominal guide steady, firmly insert the tapered end of the coupler (with attached needle) over the guide. Ensure there is a snug connection between the coupler and abdominal guide. Be sure that this interlocked system (the abdominal guide, GYNECARE TVT needle, coupler and reusable introducer) is oriented in the same plane. Using the non-dominant hand on the abdominal portion of the guide and the dominant hand gripping the introducer, **push** the system upward toward the abdomen following the curvature of the interlocked system. **The abdominal guide should not be used to pull the interlocked system upward toward the abdomen.** The interlocked system should be pushed up toward the abdomen until the tip of the GYNECARE TVT needle is visible through the abdominal incision. Disarticulate the reusable introducer and pull the remaining portion of the GYNECARE TVT needle through the abdominal incision. Cut the tape close to the needles. The exact same procedure is carried out on the other side.

Pull the abdominal ends of the tape upward to bring the vaginal aspect of the tape (sling) loosely, i.e. without tension, under the midurethra. Now, adjust the tape so that leakage is reduced allowing a few drops of urinary leakage to occur under stress. For this, use patient feedback i.e. coughing with a full bladder (approximately 300ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. **To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths.** Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. Cut the abdominal ends of the tape so that the ends are in the subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

Vaginal Approach

If the vaginal approach is used for placement of the GYNECARE TVT Tension-Free Vaginal Tape, the abdominal guides and couplers are not necessary.

Using the introducer, the needle is passed paraurethrally penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should rest in the palm of the "vaginal" hand. If you are right handed this means that the left hand generally is the one to be used for needle guidance. With the other hand, grip the handle of the introducer gently. Now introduce the needle tip into the retropubic space. Once again, observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally i.e. in the frontal plane. After passage of the urogenital diaphragm, you will feel that the resistance is significantly reduced.

Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer thereby pressing the tip of the needle against the back of the pubic bone. Now, move the needle tip upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way. When the needle tip has reached the abdominal incision, cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. Disarticulate the reusable introducer and pull the remaining portion of the GYNECARE TVT needle through the abdominal incision. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e. without tension, under the midurethra. Cut the tape close to the needles. Now, adjust the tape so that leakage is reduced allowing a few drops of urinary leakage to occur under stress. For this, use patient feedback i.e. coughing with a full bladder (approximately 300 ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths. Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape,

close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in the GYNECARE TVT implantation procedure before employing the GYNECARE TVT device. It is important to recognize that GYNECARE TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- The abdominal guide should not be used to pull the interlocked system upward toward the abdomen.
- Ensure there is a snug connection between the guide and coupler and the coupler and GYNECARE TVT needle.
- Acceptable surgical practice should be followed for the GYNECARE TVT procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should then be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the GYNECARE TVT procedure, in case of pregnancy delivery via cesarean section is recommended.
- Post operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the GYNECARE TVT procedure. To minimize this risk, make sure to place the tape tension-free in the mid-urethral position.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.

- Do not resterilize GYNECARE TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS

(GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide) To ensure the reliability and functionality of GYNECARE TVT Introducer and GYNECARE TVT Rigid Catheter Guide, clean the instruments before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments. Prior to cleaning, the GYNECARE TVT introducer should be separated into its component parts (handle and threaded shaft). The Introducer is reassembled after cleaning and before sterilization.

Manual Method:

1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86 °F to 95 °F (30 °C to 35 °C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

Automated Method:

Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water — 1 minute
- Wash 176 °F (80 °C) — 12 minutes
- Rinse Cycle — 1 minute
- Rinse Cycle — 12 minutes
- Final Rinse — 2 minutes
- Rinse with Demineralized water 176 °F (80 °C) — 2 minutes
- Dry 199.4 °F (93 °C) — 10 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS (GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide)

The GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270 °F to 284 °F (132 °C to 140 °C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

INSTRUMENT MAINTENANCE

- GYNECARE TVT Introducer
  Before each use, inspect the threaded parts of the inner shaft.
- GYNECARE TVT Rigid Catheter Guide
  Before each use, inspect the instrument. Check to ensure that the long end, which traverses the catheter channel, has no sharp edges or burrs.

HOW SUPPLIED

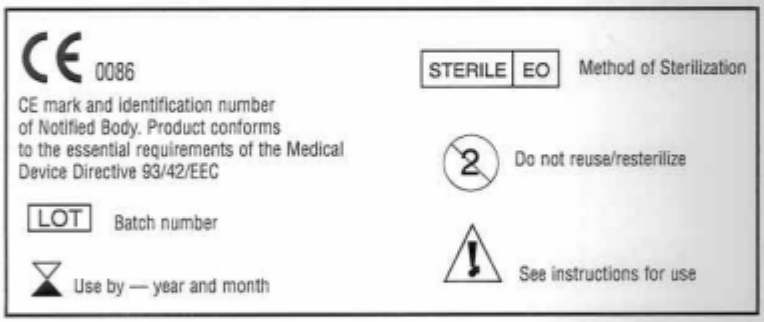
The GYNECARE TVT device and Abdominal Guides and Couplers are provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices. The reusable GYNECARE TVT introducer, GYNECARE TVT rigid catheter guide are supplied separately, and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

STORAGE

Recommended storage conditions for the GYNECARE TVT single use device are below 25 °C, away from moisture and direct heat. Do not use after expiry date.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

*Trademark



GYNECARE TVT*
Obturator System
Tension-free Support for Incontinence

GYNECARE TVT* obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT* obturatorsystem
Spændingsfri støtte til inkontinens

GYNECARE TVT* -obturaattorijärjestelmä
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT*
Dispositif sans tension contre les incontinences

GYNECARE TVT* Obturator System
Spannungsfreie Unterstützung bei Inkontinenz

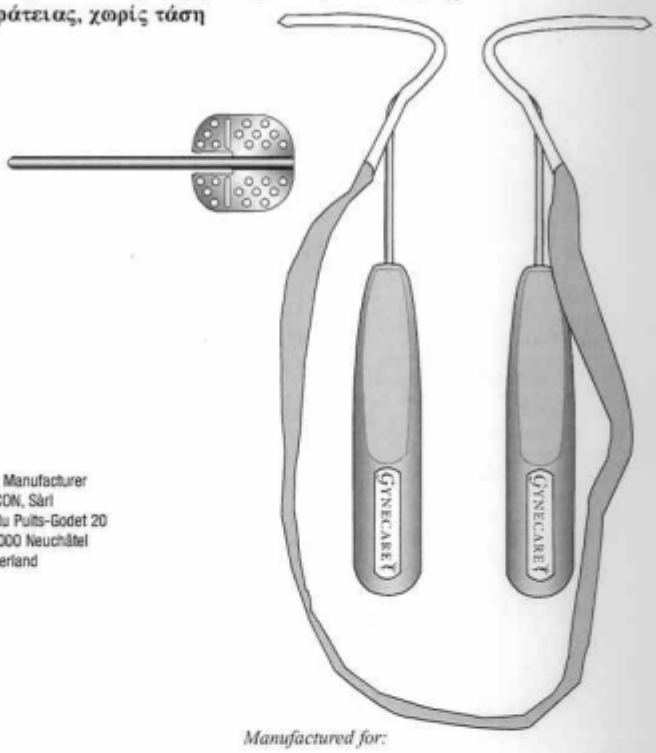
Sistema otturatorio GYNECARE TVT*
Dispositivo tension-free per l'incontinenza

Sistema obturador GYNECARE TVT*
Apoio sem tensão para incontinência

Sistema obturador GYNECARE TVT*
Protector sin tensión para la incontinencia

GYNECARE TVT* obturatoriabandsystem
Tensionsfritt stöd för behandling av inkontinens

Σύστημα επιπωματικού GYNECARE TVT*
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση



EC
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Switzerland

Manufactured for:

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Somerville, New Jersey 08876-0151

Made in Switzerland

RMC P18070/C

ENGLISH

GYNECARE TVT* Obturator System
Tension-free Support for Incontinence

GYNECARE TVT Obturator Device, Sterile Single Use

GYNECARE TVT Obturator Helical Passers, Sterile Single Use

GYNECARE TVT Obturator Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT* Obturator System, including the GYNECARE TVT Obturator device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT Obturator System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT Obturator device

The GYNECARE TVT Obturator device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color Index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT Obturator device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT Obturator device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS

The GYNECARE TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. If desired, retract the labia to provide additional exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*

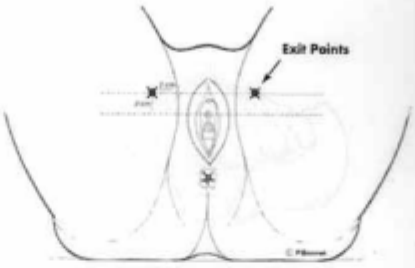

FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

After initiating sharp dissection, continue by using a "push-spread technique", to perform blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented on the horizontal plane *(See Figure 2)*. Continue dissection towards the junction between the body of the pubic bones and the inferior pubic ramus. *(See Figure 2)*

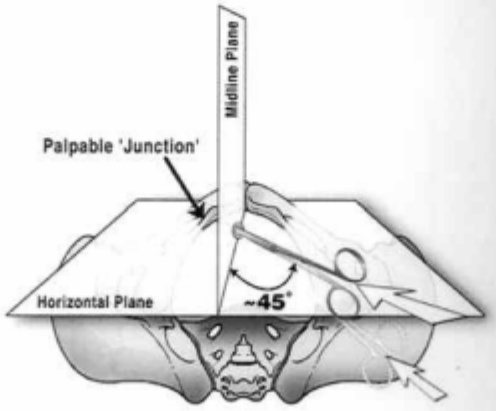

FIG. 2

When the junction between the body of the pubic bones and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the internal package workstation from the external package. Then remove the GYNECARE TVT Winged Guide from the package workstation. *(See Figure 3)*

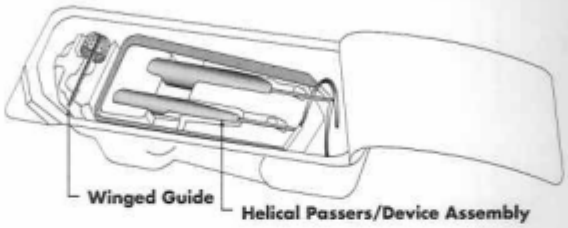

FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT Obturator device assembly from the sterile pack *(See Figure 3 for components).*

(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

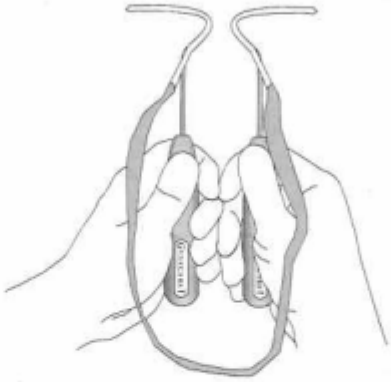

FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.

11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. *(See Figure 5)*

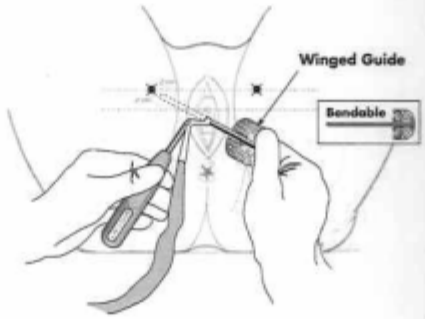

FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

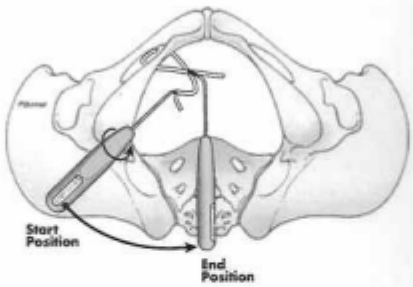

FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer as you simultaneously move towards the midline until the handle is vertical to the floor. *(See Figure 6)* ***(Note: Never allow the handle to be oriented horizontal to the floor.)***

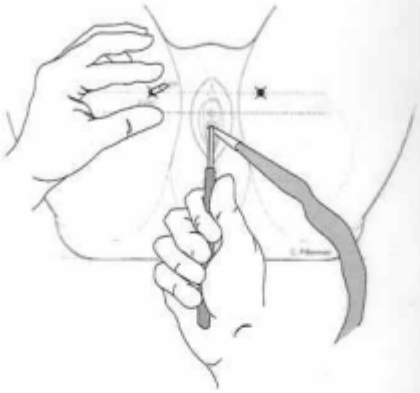

FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points *(See Figure 7)*. However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp the pointed tip of the plastic tube with a clamp and, while stabilizing the tube near the urethra with the thumb, remove the Helical Passer by a reverse rotation of the handle. *(See Figure 8)*

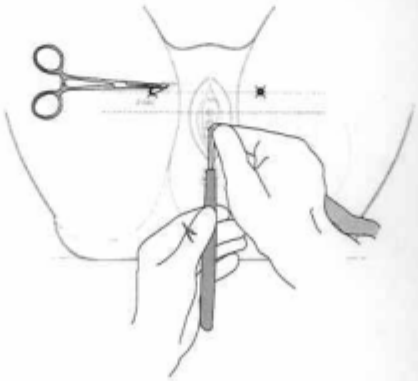

FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. *(See Figure 9)*

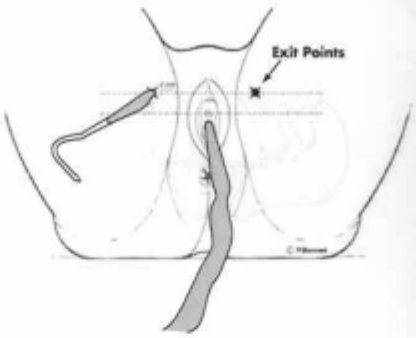

FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. *(See Figure 10)*

(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

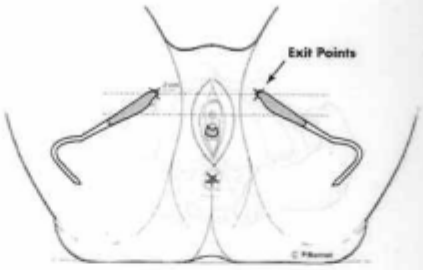

FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the midurethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. *(See Figure 11)*

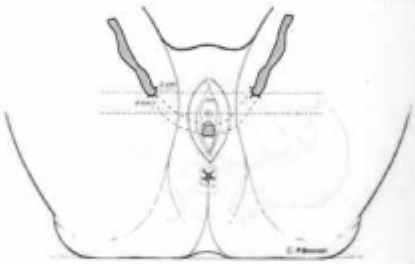

FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. Place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths, or use other suitable means during sheath removal, to avoid positioning the tape with tension.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.

19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT Obturator procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT Obturator procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT Obturator procedure before employing the GYNECARE TVT Obturator device.
- Acceptable surgical practice should be followed for the GYNECARE TVT Obturator procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT Obturator procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT Obturator System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT Obturator System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT Obturator device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

The GYNECARE TVT Obturator System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

STORAGE

Recommended storage conditions for the GYNECARE TVT Obturator System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

*Trademark

SYMBOLS USED ON LABELING

CE 0086 — CE mark and identification number of Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC

STERILE EO — Method of Sterilization

2 — Do not reuse/resterilize

LOT — Batch number

Use by — year and month

See instructions for use

Appendix D (cont.) – FDA MAUDE Database Review Summary

Sling	Brand Name	Date Report Received	Harm
BOSTON SCIENTIFIC	ADVANTAGE SLING SYST	12/19/2007	Blood Loss
BOSTON SCIENTIFIC CO	VESICA SLING KIT WIT	12/19/2007	Infection/Erosion
BOSTON SCIENTIFIC	ADVANTAGE SLING SYST	12/18/2007	No harm: Failure of Treatment
BOSTON SCIENTIFIC	OBTRYX MESH SLING SY	12/18/2007	Infection
AMERICAN MEDICAL SYS	MONARC SLING SYSTEMS	12/18/2007	Nerve Damage/Pain
BOSTON SCIENTIFIC	ADVANTAGE SLING SYST	12/17/2007	Erosion-Vagina
BOSTON SCIENTIFIC	OBTRYX MESH SLING SY	12/13/2007	No harm: Failure of Treatment
BOSTON SCIENTIFIC CO	LYNX MESH SLING SYST	12/10/2007	Erosion-Vagina
BOSTON SCIENTIFIC	OBTRYX MESH SLING SY	12/10/2007	Tissue Damage
BOSTON SCIENTIFIC	PREFYX SLING SYSTEM	12/3/2007	Nerve Damage/Pain
BOSTON SCIENTIFIC	ADVANTAGE SLING SYST	12/3/2007	Blood Loss
AMERICAN MEDICAL SYS	BIOARC SLING SYSTEM	11/30/2007	Tissue Damage
AMERICAN MEDICAL SYS	BIOARC SLING SYSTEM	11/30/2007	Tissue Damage
BARD UROLOGICAL DIVI	ALIGN TO	11/30/2007	No harm: Failure of Treatment
BOSTON SCIENTIFIC	LYNX MESH SLING SYST	11/26/2007	Nerve Damage/Pain
CALDERA MEDICAL	T-SLING	11/26/2007	No harm: Failure of Treatment
AMERICAN MEDICAL SYS	SYNTHETIC SLING MESH	11/13/2007	Infection
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
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MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
MENTOR	OBTAPE SLING	11/13/2007	Infection/Erosion
COLOPLAST MANUFACTUR	ARIS	11/9/2007	Erosion-Vagina
COLOPLAST MANUFACTUR	ARIS	11/9/2007	Erosion-Vagina
C.R. BARD, INC.	PELVILACE BIOURETHRA	11/9/2007	Blood Loss
BOSTON SCIENTIFIC	OBTRYX MESH SLING SY	11/8/2007	Erosion-Vagina
BOSTON SCIENTIFIC	LYNX MESH SLING SYST	11/8/2007	Blood Loss
BOSTON SCIENTIFIC	OBTRYX MESH SLING SY	11/6/2007	Erosion-Vagina
BOSTON SCIENTIFIC	OBTRYX MESH SLING SY	11/6/2007	Nerve Damage/Pain
TREVOUX - USS	PARIETEX UGYTEX PP P	10/31/2007	Nerve Damage/Pain
HERNIAMESH, S.R.L.	T-SLING	10/31/2007	Erosion-Vagina

FDA MAUDE Database Reported Harms Summary

Count of Harm	
Harm	Total
Blood Loss	4
Erosion-Vagina	7
Infection	2
Infection/Erosion	22
Nerve Damage/Pain	5
No harm: Failure of Treatment	4
Tissue Damage	3
Grand Total	47